



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/715,665

11/17/2003

Mark Selby

PP01635.007

5235

27476

7590

08/14/2006

EXAMINER

LUCAS, ZACHARIAH

Chiron Corporation

Intellectual Property - R440

P.O. Box 8097

Emeryville, CA 94662-8097

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,665

Applicant(s)

SELBY ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-37, 42-45, 66-69, 77 and 79-88 is/are pending in the application.
- 4a) Of the above claim(s) 80-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-37, 42-45, 66-69, 77 and 85-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 34-37, 42-45, 66-69, 77, 79-88 are pending in the application.
2. In the prior action, the Final action mailed on January 13, 2006, claims 34-37, 42-45, 66-69, 77, and 79-98 were pending; with claims 80-84 withdrawn as to non-elected inventions; and claims 34-37, 42-45, 66-69, 77, 79, and 85-88 rejected.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 13, 2006 has been entered.

In the amendment of July 13, 2006, the Applicant cancelled claim 79; and amended claims 34, 37, 42, 45, 66, 69, 77, 85, 87, and 88.

4. Currently, claims 34-37, 42-45, 66-69, 77, and 85-88 are pending and under consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained)** Claims 34, 35, 37, 42, 43, 45, 66, 67, 69, 77, 79, and 85-88 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 79 has been cancelled from the application. The rejection is

Art Unit: 1648

therefore withdrawn from this claim. The claims were rejected as lacking sufficient written description support for nucleotides encoding the genus of peptides comprising immunogenic sequences having at least about 90% identity to an HCV sequence.

Claims 34, 35, 37, 42, 43, 45, 66, 67, 69, 77, and 85-88 have been amended to read on nucleic acids, or compositions comprising such, encoding a polypeptide having at least about 90% identity to an HCV sequence, and which comprising an HCV epitope. While such an amendment may have overcome the rejection if limited to native HCV epitope sequences, it is noted that that application defines an epitope as including “sequences identical to the native sequence as well as modifications to the native sequence, such as deletions, additions and substitutions.” See, App., pages 11-12. In view of this definition in the application, which permits the modifications made to the protein sequence to be in the epitopic sequence, the amendment is not found sufficient to overcome the rejection.

The Applicant traverses the rejection on the basis that those in the art would have been in possession of the precise sequences falling within the claims, and methods for identifying such sequences and testing polypeptides for the required activity. The Applicant also asserts that, according to Example 14 or the USPTO’s Written Description Guidelines, a single disclosed species may be representative of a “product-by-function” genus when all the members exhibit structural identity to a reference compound and where an assay is provided for identifying variants having the claimed activity. These arguments are not found persuasive.

It is first noted that the present rejection extends only to the extent that the present claims read on embodiments wherein the encoded polypeptide comprises variants of the HCV sequence

Art Unit: 1648

of the HCV-1 sequence, or homologues thereof from other HCV isolates. I.e., the genus rejected is the genus encompassing non-naturally occurring variants of the indicated HCV sequence.

It is next noted that the Written Description Guidelines referred to by the Applicant are not legally binding. Moreover, they are subject to change in view of later changes in PTO policy and patent. It is additionally noted that such changes regarding the application of Written Description have been necessitated. In particular, the Court of Appeals for the Federal Circuit has indicated both that methods for the identification of compounds do not provide support for compounds that may be so identified (*University of Rochester v. G.D. Searle & Co.*, 69 U.S.P.Q.2d 1886, at 1895 [2004]); and that in situations where there is uncertainty in the operation of species other than the disclosed species, even the presence of multiple species does not necessarily demonstrate possession of the genus. See, *In re Smyth*, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating “where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application.”); and *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing *Smyth* for support). In view of the above, and as uncertainty as to the operation of other species of the claimed genus has been established in the prior action (esp., page 5 of the action mailed on January 13, 2006), the Applicant’s arguments in traversal of the rejection are not found persuasive, and the rejection is maintained.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **(Prior Rejection- Withdrawn)** Claims 79 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the cancellation of this claim, the rejection is withdrawn.

9. **(Prior Rejection- Withdrawn)** Claim 87 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was unclear which of the complete S domains in claim 85 was being referred to in claim 87. In view of the amendment of the claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Maintained)** Claims 34-36, 42-44, and 66-68 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Major et al. (J Virol 69: 5798-5805- of record in the Nov. 2003 IDS) in view of Michalak et al., (J Gen Virol 78: 2299-2306), and further in view of Valenzuela et al. (Bio/Technology 3: 323-26- also of record in the Nov. 2003 IDS).

It is first noted that the Applicant asserts that the Examiner has misrepresented the teachings of the Major reference. In this, the Applicant refers to the Examiner's response to

Art Unit: 1648

earlier arguments by the Applicant regarding the teachings of this reference. The Examiner nowhere indicates that the Major reference specifically teaches that the making or use of a fusion protein comprising and HBsAg and an HCV E2 protein. To the extent that the Applicant's arguments are based on this asserted misreading of the Major reference, they are therefore not found persuasive.

The Applicant next provides a listing of the various references individually, and asserts that no combination of the references meets all of the claim limitations. It is noted that arguments attacking individual references in an obviousness rejection based on a combination of references is not a persuasive argument. See e.g., MPEP 2145 § IV. This argument is not found persuasive as the Applicant has nowhere considered the teachings of the reference cumulatively, or identified what limitations are not met by the combination of the references.

Because the Applicant's arguments are based on the failings of the individual references, and fail to consider what would have been obvious to those of ordinary skill in the art based on the combination of the references, the arguments in traversal are not found persuasive and the rejection is maintained for the reasons above and the reasons of record.

12. **(Prior Rejection- Maintained)** Claims 77 and 79 were rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (U.S. 6,306,625), in view of Major, Michalak, and Valenzuela as applied to claims 34-36, 42-44, and 66-68 above. The Applicant traverses this rejection on the basis that Jacobs does not teach or suggest the fusion of HBsAg with an HCV antigen. This argument is not found persuasive in view of the inclusion of the Major and

Art Unit: 1648

Michalak references in the statement of the rejection, and for the reasons indicated above with respect to claims 34-36, 42-44, and 66-68.

13. **(Prior Rejection- Maintained)** Claim 37 was rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Major, Michalak, and Valenzuela as applied to claim 77 above, and further in view of the teachings of and GenBank Accession Numbers X02763, and M62321. The Applicant traverses the rejection based on the assertion that the cited art provides no motivation to combine an HBsAg sequence with an HCV E2 sequence. In view of the inclusion of the teachings of the Major and Michalak references as described previously and above, and for the same reasons as indicated with respect to the teachings of Major and Michalak in the rejection of claims 34-36, 42-44, and 66-68 above, this assertion is not found persuasive. The rejection is therefore maintained.

14. **(Prior Rejection- Maintained)** New claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Major, Michalak, and Valenzuela as applied to claims 77 above, and further in view of De Wilde et al. (U.S. 5,928,902), U.S. 4,722,840 (the 840 patent- of record in the November 2003 IDS), and Mountford et al (PNAS 91: 4303-07).

The Applicant traverses this rejection for the reasons indicated above, and on the basis that there is no motivation to combine the elements identified in the references. In particular, the Applicant asserts that there is no motivation to combine the teachings of Major, which teach a nucleic acid encoding HBsAg and the HCV nucleocapsid antigen, with the teachings of

Art Unit: 1648

Michalak, which teaches that the indicated HCV E2 antigen “is the best candidate for a soluble form” of E2.

It is noted that, in addition to these teachings, the both the Major and Michalak reference are teaching the making and use of anti-HCV immunogenic compositions. In view of the fact that Major is teaching the use of the HBsAg protein as a carrier for an anti-HCV antigen, and as the Michalak reference teaches an HCV antigen for use in the induction of an anti-HCV immune response (as described on pages 6-8 of the action mailed on July 29, 2005), those in art would have had sufficient motivation to combine these teaches to use the HBsAg protein as a carrier for the anti-HCV antigens of Michalak. Moreover, it is noted that in these references, both the HCV core (Major) and E2 proteins (Michalak) are identified as anti-HCV antigens. It would therefore have been prima facie obvious to substitute one of these antigens with the other. See e.g., MPEP 2144.06. Thus, for either of these reasons, those of ordinary skill in the art would have been motivated to combine the teachings of the indicated references.

Those in art would also have been motivated to combine the teachings of the additional references for the reasons indicated in the prior actions. The Applicant’s arguments in traversal are therefore not found persuasive, and the rejection is maintained.

15. **(New Rejection)** Claims 88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Major, Michalak, and Valenzuela, further in view of De Wilde et al. (U.S. 5,928,902), U.S. 4,722,840 (the 840 patent- of record in the November 2003 IDS), and Mountford et al (PNAS 91: 4303-07) as applied to claims 85-87, further in view of the teachings of GenBank Accession Numbers X02763, and M62321 as applied to claim 37. Claim 88 is

Art Unit: 1648

drawn to the vector of claim 85, wherein the nucleotide sequence comprises the sequence of nucleotides 1992-3584 of SEQ ID NO: 6, or a nucleotide having at least about 90% identity thereto. Because each of the limitations of this claim is met by the teachings of the combined references (as described above and in the prior actions), these references would have rendered the claimed invention obvious to those of ordinary skill in the art.


Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas 8/5/06
Patent Examiner